EXHIBIT D

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327
	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
THIS DOCUMENT RELATES TO THE FOLLOWING CASES IN WAVE 1 OF MDL 200:	
Angela Coleman, et al. v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-01267	
Mary F. Cone v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-00261	DEPOSITION OF ROBERT D. MOORE, D.O.
Teresa Georgilakis, et al. v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-00829	April 15, 2016
Dawna Hankins v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-00369	
Margaret Kirkpatrick v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-00746	
Carrie Smith v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-00258	

Isabel Swint v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-00786

DEPOSITION OF ROBERT D. MOORE, D.O.

April 15, 2016

9:42 a.m.

Suite 1560
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Reported by: F. Renee Finkley, RPR, RMR, CRR, CLR, CCR-B-2289

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Q. (By Ms. Maimbourg) Doctor, I've handed you what has been marked as Exhibit 9, and it's entitled Potential Risks of Non-Mesh and Mesh SUI Surgeries. Just take a look at it and let me know when you're done.

A. Okay.

Q. So just with respect to the column on the right that's entitled Mesh, do you agree that the right -- that this column lists the risks of mesh surgeries?

MS. MARIGLIANO: Object to the form.

THE WITNESS: Yes, I do.

Q. (By Ms. Maimbourg) And do you agree that any -- if any of these risks develop, that the effect on the patient could be temporary or chronic?

A. Yes.

Q. And do you agree that if any of these risks developed, the effect on the patient could be mild, moderate, or severe?

A. Yes, I do. Relative risks aren't listed certainly here on this chart, so that would be one issue that I'd have with the chart, just listing out complications without putting down actually the relative risks of the different complications.

Q. Okay. If we have time, we'll go back over that. You know what? Before we move on, I do want to mark three articles that you brought with you today, and I'm just going to have you identify them for the record. What is Exhibit 10, Doctor?

(Exhibit 10 was marked for identification.)

THE WITNESS: This is an abstract that we presented at the American Urogynecology Society meeting in 2014 on Indication of Surgical Treatment of Midurethral Sling Complications, a Multicenter Study.

Q. (By Ms. Maimbourg) Is that -- was that mentioned in your report?

A. Yes.

Q. And then Exhibit 11 is also the same data presented at a different time?

(Exhibit 11 was marked for identification.)

THE WITNESS: No, it's basically just a sub-analysis of the data that this first one that we talked about, Exhibit 10, is just about slings. This one is talking about specifically either slings or pelvic organ prolapse

indications for removal, and then --

(Exhibit 12 was marked for identification.)

Q. (By Ms. Maimbourg) And then Exhibit 12, you also brought this?

A. Exhibit 12 is kind of the main study that actually classifies every patient that came in with a mesh complication, utilizing the IUGA/ICS classification of synthetic mesh complications of all of these patients. So the first one is just classifying the different complications via the official IUGA/ICS classification system.

Q. When you said the first one, you were actually holding Exhibit 12?

A. Exhibit 12, yes.

Q. Right. So are all of these -- and I apologize, 'cause I didn't have those first two abstracts before today. Is the data in 10 and 11 also in 12? No, is that -- partially?

A. Yes, I would say all of the patients -- it's the same patient population from three centers, our center, Emory University, and Cleveland Clinic, Florida. All the patients, all the mesh complications are the same in each of these papers.

However, 12, which is really the main paper -- 10 and 11, Exhibit 10 and 11 are sub-analysis of this data.

Q. That helps a lot. Keep those there, because I will ask some questions about 12. Just stick them up there. All right.

(Exhibit 13 was marked for identification.)

Q. (By Ms. Maimbourg) I'm going to mark as Exhibit 13 --

(Discussion off the record.)

Q. (By Ms. Maimbourg) Doctor, this was printed on April 12th of 2016, if you could see that date on the top left of this document. Could you identify what this is?

A. This looks like a page from one of our websites.

Q. And actually, it's the International Center For Laparoscopic Urogynecology, right?

A. Yes.

Q. And that is one of the names of your practice?

A. Yes.

Q. So in this section on TVT sling complications, the first sentence says, Although the

TVT sling is considered the standard of care, complications can still occur. That's what it says, right?

A. Yes.

Q. And are you referring to any particular type of sling in that sentence that you say TVT?

A. I mean, we're using it more generically as a retropubic midurethral sling.

Q. Would a standard -- strike that.

The second sentence says, It is very important to note that it may not be the mesh itself or the procedure that is the cause of the complication. It may be how the mesh is placed or how the body heals around the mesh that may be part of the underlying cause. That's on the -- your website page today, right?

A. This is actually -- I guess it's still available. I mean, this is an older version of our website, but if you just printed it April 12th, I guess it's still out there and available, so --

Q. Well, is this still your opinion today?

A. Yes, I think we've updated it on our new website as well to say as well, that it certainly depends not only on those factors, but also the

portion of that website, but this -- our new website has been in the makings for at least a year.

Q. In terms of mesh removal, which you describe on page 6 of your report, you have a couple different numbers there, and I just wanted to clarify in my own mind.

MS. MARIGLIANO: I'm sorry, what page?

MS. MAIMBOURG: Six.

Q. (By Ms. Maimbourg) Are you there?

A. Yes.

Q. So if you go down to the bottom, it says, My partner and I have explanted more than 700 mesh devices, with more than 500 since 2010?

A. Uh-huh.

Q. And then up above, on the very first part, you said, More than 500 pieces in the last four years. And since four years would actually be 2011 through 2015, I just wanted to clarify what the accurate numbers are.

A. I would say the accurate numbers are this down here below, because we know -- you know, basically, we've got very good numbers based from the study from the years 2011 to 2013, in which there was 500 pieces of meshes explanted in this trial. We did

75 percent of those from the three centers, so that was over 300, we've explanted in the last two years. Approximately about a hundred to 120 each year. And so then, prior to 2010, from 2002 through 2010, you know, there was least 200. I don't have those exact numbers.

Q. Of the ones that you've removed, you list here that they've included Gynecare Prolift, Prolift Plus M, Prosima, TVT retropubic, TVT-O, and TVT-Secur slings. I just want to make sure that you are not saying the only mesh devices you've removed are those products; is that true?

A. That is true.

Q. So you've just listed the Ethicon products, but you've also removed products of other manufacturers, true?

A. Yes.

MS. MARIGLIANO: Can we take a break, if you're at a good stopping point?

MS. MAIMBOURG: Sure. Yeah, let's take a break. We've been going about an hour.

(A recess was taken.)

Q. (By Ms. Maimbourg) Doctor, we're back on the record. I've asked you to look at your

Exhibit 12, which is the data you were referring to, I think, in one of your last answers. So this multi-center study, you already identified the three institutions. You and your partner removed 373 slings, right?

A. Yes.

Q. And that's actually on page 2, you have that data. And in this article, you do not breakdown the type of slings by number, correct?

A. Correct.

Q. And I take that that you removed retropubic single incision TOT inside-out and TOT outside-in?

A. Correct.

Q. Do you have that data somewhere?

A. It's actually in that -- one of those abstracts that we talked about earlier, that's specifically on mesh itself. I believe if you take a break at it, what we've broken down --

Q. Let me ask you this. Does it include a breakdown of how many TOT slings were inside-out versus outside-in in this study?

A. It does not.

Q. Is that data somewhere back at Atlanta

Research, Inc.?

A. If it's available, yes.

Q. Do you believe it's available?

A. I don't know how many numbers of patients that we actually have identified inside-out versus outside-in.

Q. In this article, you do not draw any conclusions about pain being worse in the patients with TOT inside-out compared to any other sling, do you?

A. No, we do not.

Q. You also do not reach any conclusion to a reasonable degree of certainty as to how the mesh was causing pain, correct?

A. In this particular study?

Q. Yes.

A. No.

Q. In terms of conflict of interest information on the last page, you say, none, right?

A. Correct.

Q. What is the purpose of the conflict of interest provision in medical literature?

A. To provide readers any potential bias that may be involved.

Q. Did you disclose here that you had testified at least nine times for plaintiffs alleging injuries from pelvic mesh, including slings?

A. No.

Q. Do you believe that a reader of this article is entitled to know that you have been and are continuing to be an expert for the plaintiffs suing mesh manufacturers?

MS. MARIGLIANO: Object to the form.

THE WITNESS: It's not part of the requirements as far as they bring you through a very stringent bias -- or not bias, but disclosure and conflict of interest form. And it's not part of the disclosure process of this journal, or any other journal that I know of right now.

Q. (By Ms. Maimbourg) So you don't believe that it would be important, regardless of the process you went through with this journal, you don't believe it's important for readers of this article to know that you're testifying on behalf of plaintiffs in pelvic mesh litigation involving the very products you are studying?

MS. MARIGLIANO: Object to the form.

page 9, which you have labeled number 1, design defects. The first thing you say in your heading is, Tendency to cause pain, and bladder, bowel, and sexual dysfunction secondary to location of mesh.

What is it about the location of the mesh that creates this tendency? And if you could be brief, I would appreciate it.

MS. MARIGLIANO: Object to the form. Answer as completely as you need to.

THE WITNESS: Well, as briefly as, or as elongated as it may be, specifically, with the transobturator sling or location of the mesh in the periurethral tissues extending out through the obturator muscles, the adductor longus muscles themselves, specifically with the TVT-O having more mesh in the adductor muscles themselves, with that type of placement of the mesh, it's been noted over time that with contraction -- with contraction, ultimately, that can cause pain.

It then causes pelvic floor dysfunction, because of dyssynergia and spasms throughout the muscles that can affect bowel, bladder function, and sexual function throughout the vagina and

the pelvis.

Q. (By Ms. Maimbourg) So my question was only about the location. So you told me your whole opinion, right?

MS. MARIGLIANO: Object to the form.

THE WITNESS: Yes, but the location of the mesh in the periurethral tissues, as well extending out into specifically with the TOT and TVT-O, obturator internus, externus adductor muscles.

Q. (By Ms. Maimbourg) So in other words, as I understand that, it's where the mesh is lying, and it's the technique of getting it there that you are calling here as a defect?

A. Yes, it's not only where the mesh is lying, but also how it's placed specifically with the TVT-O device, which includes the needles and the mesh itself.

Q. In these two pages, and I'm basically going through this the way you have set it up.

A. Okay.

Q. So in these two pages, subsection A, am I correct that you cite nothing for the proposition that the location of the mesh has a tendency to cause

pain, bladder, bowel and sexual dysfunction?

MS. MARIGLIANO: You're just saying in subsection A, you're asking if he said that or if he --

MS. MAIMBOURG: Correct.

MS. MARIGLIANO: -- didn't include that?

MS. MAIMBOURG: That's exactly what I'm asking, in these two pages.

MS. MARIGLIANO: I'm just going to object to the form.

THE WITNESS: What I'm describing is the -- in those two pages, and it gets into specifics as far as where the mesh is implanted and how it causes complications at the bottom of page 10, and subset of B. In A itself, it's just describing the placement of the initial TOT, and then the subsequent development of the TVT-O, and how that is placed itself.

Q. (By Ms. Maimbourg) So in these two pages under subsection A, you don't cite any medical literature for the proposition. You cite that in other parts of your report?

A. Yes.

MS. MARIGLIANO: Well --

Q. (By Ms. Maimbourg) So B --

MS. MARIGLIANO: Object to the form.

Q. (By Ms. Maimbourg) B is entitled, Mesh Implanted in Groin Muscles Causes Complications, and it's essentially one paragraph, right?

A. Yes.

Q. And you say here that the mesh -- bottom of 10 -- these transverse mesh arms damage the levator and obturator and adductor muscles. And so I'm going to stop there, and ask you, what is your support for that statement that the arms damage those muscles?

A. The subsequent papers and literature that have been -- that have described patients that have prolonged groin pain, thigh pain, vaginal pain, dyspareunia from the mesh arms lying within these muscle groups themselves.

Q. Can you identify those articles?

A. Sure. I mean, as far as if we want to take a look at long-term complications, meaning at least pain of any kind of subsequent nature, or having pain, then we can start with some of the initial trials, the de Leval initial trials that basically they relied upon, who's the inventor of the

product, 26 percent groin pain. They didn't really track that out.

And then as the papers started coming out in the literature, including Laurikainen's original paper, I think was 2007 in the Green Journal of OB/GYN, groin pains of 16 percent at a year, 5 percent persistent groin pain, which is still significantly impacting women at that point in time. And then we can list Yik Lim and Marcus Carey, the same amount -- actually, 24 percent short-term pain, 4 percent long-term pain.

Q. You know what? We'll get into -- are these all cited in your report, 'cause --

A. They are.

Q. -- we'll probably get into some of them.

A. They are.

Q. Do you mind if I move on, and we can talk about them as they come up?

A. Sure.

Q. All right. I wanted to ask you, though, with respect to the definition of prolonged pain, which that's the term you used in your answer, could you tell me your understanding of what that is versus what is postoperative pain? And in your mind, is

there a difference in this analysis?

A. Yes, I mean, I think really any type of postoperative pain should be resolved by six weeks and 12 weeks, probably at the latest. Anything that is beyond that, I believe becomes more of a prolonged pain issue. And certainly something that's going beyond six months to one year is more of a persistent type of pain issue.

Q. So at the top of page 11, you say, If pain results in the levator ani region secondary to the mesh -- what did you mean, secondary to the mesh?

A. Specifically, if there's a mesh arm in that muscle creating contraction, creating fibrosis, a chronic inflammatory reaction, that creates shrinkage of the mesh in the surrounding tissues that creates nerve entrapment or pain for any of those reasons, then that's going to ultimately affect the muscles throughout the pelvic floor.

Q. Now, in this paragraph, same paragraph where we're talking, you do cite the Cochrane review showing -- you say, overall rates of groin pain higher in the TOT group, right?

A. Yes.

Q. You cite the Cochrane review. Now, does

the Cochrane review give a probable explanation or reason for this, or is it just reporting the statistics?

A. The Cochrane review is considered probably the kind of leading authority on data analysis from high level studies, evaluating all of the literature that's been reported.

Q. So is it just reporting the statistics or is it giving a probable explanation?

A. It reports the statistics.

Q. So can you cite to me any article -- and again, we can maybe get into this, but as you sit here right now, in this part of the deposition, can you cite to me any article that has verified, through a scientific process, your previous answer about how the mesh arms in the muscle cause pain through various mechanisms, where that has been proven?

A. I mean, there's many, many articles that describe chronic pain in this region secondary to TVT-O slings, and many come up with scientific reasoning behind it. So I'm not sure really what your -- what your question is, as far as to how you can specifically state the kind of scientific reasoning behind that.

Q. Well, I'll explain to you what I mean. Many of the articles you cite here, which I've read, refer to possibilities. They use the word "may," they use the word "can," and I have not found in any of the articles on your reliance list that you cite, where an author in a scientific publication has said, to a reasonable degree of medical probability, or similar words, that the mesh arms in the muscles are causing the type of contraction and scarring that you believe, in your opinion, causes the pain. Have I missed something, is there an article that does that?

MS. MARIGLIANO: Object to the form.

THE WITNESS: Well, I think that basically journal articles, and journals themselves, the verbiage that is required is different. That is what that particular author is stating. They also would state that if the mesh wasn't there, certainly the patient wouldn't have pain in that specific location.

So there's been multiple studies that have looked at anatomical directions of this mesh, where it's going, the TVT-O in relationship to the obturator nerves. Also saying why are these patients in the TVT-Os having more groin pain

than those that don't have mesh in that specific area.

And so although they may say "may" or "perhaps" or "theoretically," which is verbiage that journals, medical journals require, it's in my opinion, to a medical degree of certainty, that this is what's causing these complications.

Q. (By Ms. Maimbourg) And what is your personal opinion based on?

A. My personal opinion is based on the -- my medical training, my experience, my taking care of patients with these type of complications, implanting and doing research trials on every type of avenue that you can with midurethral slings. And knowing that we don't see groin pain in patients that have a retropubic sling that is similar to this type of a pain, when the mesh is in the muscle or irritating the nerve directly.

Q. Doctor, on page 12 of your report, when we're talking about pain syndromes, one of the articles you cite several times in your report is Teo. Did I say that right? Is it -- it's T-E-O?

A. Correct. I'm not sure of the pronunciation.

Q. I was wondering if we could go off the record for a minute, so you could locate that in your binder?

MS. MARIGLIANO: We can -- it's -- oh, it's in there.

THE WITNESS: No, it's right here.

MS. MAIMBOURG: I don't how long it's going to take.

(Discussion off the record.)

Q. (By Ms. Maimbourg) What is the publication date on the bottom, to the right?

A. 2011.

Q. No, the month?

A. April.

Q. All right, so -- 'cause you have February cited here, and I wanted to make sure that I have the same article. Let me see yours, just to make sure it's the same as mine. Yes, it is. Okay. Doctor, I'm actually going to mark my copy, so you can put yours back in your notebook?

(Exhibit 17 was marked for identification.)

Q. (By Ms. Maimbourg) And you describe on page 12 of your report that this trial by Teo -- do

you think that's how he pronounces it? T-E-O? How would you pronounce that? You don't know?

A. I would have say Teo.

Q. Teo. All right. So you say in your report on page 12, This trial -- I believe you're talking about this trial, Teo -- was perhaps the clearest example of the clinical and scientific impact of pain syndromes caused by the TVT-O, and comes from the results of an independent study that was performed by several of Ethicon's KOLs. So that's what you're referring to, Teo, right?

A. Yes.

Q. Now, you say in your report that the investigators stopped the trial, because of excess pain reports in the TVT-O arm, and you put in parentheses, 26.4 percent pain reported at six months, right?

A. Yes.

Q. And I think you actually referred to that in one of your previous answers. So I'd like you to go to page 1351 of the article, under the section that's entitled, Results. Are you there? Results, 1351?

A. Yes.

Q. The second paragraph that says, during recruitment? Are you there?

A. Uh-huh.

Q. This paragraph says, During recruitment, a few studies were published showing similar cure rates for the two procedures, meaning obturator and retropubic, but a high incidence of leg pain in patients after receiving a transobturator tape. After discussing these data at an investigator meeting, we decided to stop recruitment before the full calculated sample was recruited, since it was deemed that clinical equipoise had been lost?

A. Correct.

Q. So the study was not stopped, as you state, because of excess pain reports in the TVT-O arm; is that true?

A. I believe it was due to the pain that they were seeing as well as the discussion they had based on that, and the literature that was in the -- that had been being published.

Q. Well, in fact, that's not what that paragraph says under Results, does it?

A. No, but I believe in the discussion, they talk about that as well.

Q. And then you say in your report that the authors concluded it was no longer ethical to use the TVT-O device, given the clear negative impact on patient health. And if you look at the Results section, where we just were a minute ago -- you're there, you're on the right page.

A. Okay.

Q. It says, We believed it was no longer ethical to randomize women to the TVT-O arm, in light of these published studies --

A. Correct.

Q. -- but data on women already recruited would be of value, right? Those two sentences are different, are they not?

A. They're saying that those -- that it would still be of value, that they were already -- that those patients were already implanted and certainly -- but they're not going to implant anymore, they're not going to recruit anymore. So I don't know whether or not these patients had already been implanted or not.

Q. I guess it would be an unfair reading of your report for anyone to believe that you were saying here that the authors of this article believed

it was unethical to use the TVT-O device, that would be an unfair reading of your statement.

MS. MARIGLIANO: Object to the form.

Q. (By Ms. Maimbourg) Right?

A. I think that what the authors are saying is that they believe that it's unethical to implant and/or recruit any more patients to continue this patient trial, and implant anymore TVT-Os. And that based on their review of the literature and their initial findings of a very high amount of groin pain in those patients.

Q. All right. In the conclusion of the article, on page 1355, the authors state, Short-term cure rates at six months are similar for the two procedures. TVT-O results in a higher level of postoperative and leg pain, although these problems are transient. And then it says, The two procedures have a high cure rate with a low rate of complications, right? Right?

A. Yes, that's what it states.

Q. All right. So you, in your report, several times quote a concluding message that I cannot find in this article. And that concluding message says, in your report, page 12, Given the

comparable efficacy of the procedures, it seems preferable to recommend retropubic tape placement to avoid a high incidence of leg pain. Can you tell me where in the article it says that?

MS. MARIGLIANO: I'm going to object. He's not saying he's quoting that.

Q. (By Ms. Maimbourg) Well, can you tell me, even if you're not quoting it, can you tell me where in the article, the authors state, it seems preferable to recommend retropubic tape placement, or is that your conclusion, your own concluding message?

A. I mean, I'd have to go through this, you know, kind of line by line to take a look at the -- the last paragraph -- to take a look at, you know, their exact verbiage throughout the thing. I don't know if I'm quoting them, if you're saying you don't see those exact words throughout there, I'll take your word on that. But if -- that was my conclusion as well as their summaries of their discussion and their results.

Q. (By Ms. Maimbourg) So if you quote something usually in your report, you would have it as a single-spaced indented quote, right?

MS. MARIGLIANO: Object to the form.

THE WITNESS: It may be, or it's in quotations.

Q. (By Ms. Maimbourg) Well, take a look at page 40 of your report, where you also quote this article by Teo, the concluding message?

A. Okay.

Q. Are you on page 40 looking at it?

A. Uh-huh.

Q. Does that look like a quote to you? The way it's set off, single-spaced indented?

A. Again, I don't know specifically if this paragraph was supposed to be a quote directly from the article.

Q. In terms of the leg pain, you say here, this -- we're on page 13 in your report, This article was not the first to show that TVT-O caused leg, groin, thigh pain in more than one in four women who were implanted, right?

A. Yes.

Q. And this study that we've been talking about, the Teo study, involved 127 women. And, in fact, if you look at the page 1354, they do say that leg pain was experienced by 26.4 percent of women in the TVT-O group, right?

A. Yes.

Q. And the article also says, The problem resolves spontaneously within three months, right?

A. Correct.

Q. And that would be within the postoperative period that you previously defined?

A. Yes, in their particular study.

Q. So this study, in particular, does not support your statement, or your claim that this leg and groin pain can be severe, chronic, life-long, and debilitating, does it?

MS. MARIGLIANO: Object to the form.

THE WITNESS: Not the particular study, but if you continue on in the discussion, they do have verbiage that does talk about those concerns. And actually, a couple of the papers we just talked about, including Laurikainen, as well as Yik Lim, as well as the Latthe meta analysis as well.

Q. (By Ms. Maimbourg) This study does not give any support for your claim that it's the proximity of the sling to nerves that is responsible for causing the pain, does it?

MS. MARIGLIANO: Object to the form.

THE WITNESS: This study basically shows that when you place mesh tape into the groin muscles, it can cause a significant amount of albeit postoperative pain in this particular patient population, but also lead to longer periods of pain that's been shown in other studies.

Q. (By Ms. Maimbourg) The purpose of this study was not to prove that, and it doesn't show it, right?

MS. MARIGLIANO: Object to the form.

THE WITNESS: Well, the purpose of this study may have been to prove it, and take a look, but they stopped the study, and didn't look at patients beyond six months.

Q. (By Ms. Maimbourg) I'm not talking -- my last question, I apologize if it was not clear, but I really wasn't talking about longevity. I was talking about mechanism.

A. Okay.

Q. And, you know, the authors of this article talk about possibilities, and they don't talk about -- they don't give an opinion in this article, and they don't prove an opinion as to what is causing

this postoperative pain, is that true?

MS. MARIGLIANO: Object to the form.

Q. (By Ms. Maimbourg) The only statements are on page -- at the top of 1355, talk -- talks in terms of possibilities?

A. Yeah, and they -- but they do go on to say that cadaveric studies have revealed that the tape passes much closer to the obturator nerve using the inside-out than the outside technique. This could possibly cause the obturator nerve to be more susceptible to damage, inflammation and edema, resulting in pain. Neuropathy resulting in gait abnormality and numbness has also been reported, and seems to be associated more with the inside-out technique.

So I think they are giving their opinions as to what the cause of pain is in this TVT-O procedure.

Q. So they're talking about possibilities here, correct? That's the word they use?

A. They are certainly talking about possibilities and utilizing their expertise in being researchers, clinicians, experts in urogynecology to say what is the potential cause of this pain.

Q. So researcher -- researchers are fundamentally scientists, right?

A. Yes.

Q. And they deal in possibilities and probabilities?

A. They do. And when they're writing for --

Q. I didn't have a question.

A. Okay.

Q. And, in fact, in your report, you say your opinions you hold to a reasonable degree of medical certainty, I think you used the term, right?

A. Yes.

Q. And you're not giving opinions to possibilities, right?

A. I'm giving opinions, based on a reasonable degree of medical certainty, which in this instance, we're taking a look at risk versus benefits, and risks outweighing benefits with the TVT-O procedure. And some of these journals hold a higher degree of probability and require that to be able to say certain verbiage. So this is why investigators will say these types of -- utilize this type of language in their studies.

Q. So maybe if these authors had put in the

word probable, their article may not have been accepted, because it would not have passed the peer-review process, because it's bad science, right?

MS. MARIGLIANO: I'm going to object to the form. You're confusing legal verbiage with verbiage that's using medical in articles.

MS. MAIMBOURG: You're not allowed to make speaking objections, I'm sorry.

MS. MARIGLIANO: So that's my objection.

THE WITNESS: Well, we don't know that.

Q. (By Ms. Maimbourg) We don't know that. We would be speculating, right?

A. Yes.

Q. So let's move on to page 13 through 24 of your report, which is the next section, quite long. And it's entitled, Inside-Out Technique of TVT-O Increases Risk of Nerve Injury/Pain. So when I look at this section, particularly page 14, and I'm looking kind of down here at the bottom, I think what you're saying here is that the technique of inserting the TVT-O puts it too close to certain nerves, which could actually damage the nerve at implantation or be close enough, so that fibrosis around the mesh could very easily cause nerve damage and pain. Does that

sort of summarize what you're saying about this inside-out technique?

MS. MARIGLIANO: I'm just going to object to the form.

THE WITNESS: It's -- yes, it's talking about one aspect of the -- of the pain.

Q. (By Ms. Maimbourg) And this defect has to do with the technique of implanting the product. And in this particular part of your opinion, you're not talking about the product itself, you're talking about the technique of implanting?

A. Well, I'm talking about the product, because the product involves the implantation process of going from the inside-out. It's part of the product, it's part of the device as all -- all of the different components of it are.

Q. So you're defining the technique as the same as the product?

A. The technique is part of the product. This particular product was the only one that was developed to go from inside to outside. And specifically, the way that it's placed, including all of the components of the product, including the metal wing tip guide, the needles, the mesh, the sheath are

all part of the procedure.

Q. Right, but you're -- the title of this section of your report is, The Technique of TVT-O Increases Risk of Nerve Injury/Pain, right? That's how you titled it?

A. Correct.

Q. All right. And in part of this section, you quote an article by Piet Hinoul, and I believe you say on page 15 -- well, take a look at what you say there. Are you there in the report?

A. Yes.

MS. MARIGLIANO: I'm not there. Oh, you're talking about on page 15, okay, I see.

Q. (By Ms. Maimbourg) So you quote him to -- that he states that, The suspicion that the inside-out procedure is linked to more neurological injuries was already raised in de Leval's original article. A recent review of the data collected by the MAUDE database also implies more pain, et cetera, et cetera, right?

A. Yes.

(Exhibit 18 was marked for identification.)

Q. (By Ms. Maimbourg) I'm handing you that

article that you've quoted, and I'd like you to go to page 1205, so we can read the rest of the quote. Could you go to page 1205, I'm sorry.

A. 1205 is the first page.

MS. MARIGLIANO: Look up here (indicating).

THE WITNESS: Okay. Got it. Okay.

Q. (By Ms. Maimbourg) The column on the left, I'm going to show you mine. See this green, that's where you quoted?

A. Okay.

Q. Okay. And I'm going go to after that quote. After the quote about the MAUDE database, Dr. Hinoul says that the MAUDE database needs to be interpreted cautiously, as no incidence rate can be derived from them, and reporting bias cannot be accounted for.

Do you agree with that, with respect to the MAUDE database?

A. I would agree that incident rate cannot be derived from them, and reporting bias also cannot be accounted for.

Q. And then he goes on to cite an article by Debodinance that was a non-randomized prospective

study compared outside-in Monarc to inside-out TVT-O, and found no difference in thigh pain between both groups, right?

A. He did.

Q. And that -- and that article would be contrary to your opinions in this case that the inside-out approach causes an increase of pain over the outside-in, right?

MS. MARIGLIANO: Object to the form.

THE WITNESS: Not necessarily. I mean, there's one study that he quotes, and there's probably a couple more that show the same amount of groin pain in the inside-out versus the outside-in. However, there's multiple -- more studies that also show an increased amount of pain with the inside-out versus the outside-in.

So he's quoting one particular study and there may be a couple more, but I can probably quote more studies overall that show a higher rate of pain with inside-out TVT-O versus outside-in approach.

Q. (By Ms. Maimbourg) You did not choose to put the Debodinance article in your report, because it doesn't support your opinions, right?

MS. MARIGLIANO: Object to the form.

THE WITNESS: The Debodinance article is part of the list of papers that's in my -- that's in -- that's in my reliance list.

Q. (By Ms. Maimbourg) Was that one that you put there, or did the plaintiffs give it to you?

A. The Debodinance? I don't know.

Q. You also talk about the Haddad article on page 15 and 16?

A. Yes.

Q. You have a lot of quotes from there. I'll pull it out and mark it, but -- if you want. It seems to me that all the quotes that you have here are merely the author's regurgitation of certain articles, and do not scientifically establish the truth of anything they're saying.

MS. MARIGLIANO: Object to the form.

THE WITNESS: Well, I wouldn't say -- again, I mean, we're getting into these discussions about what's science and what's truth, and what's a reasonable degree of certainty. That's the verbiage that's used in literature and journals versus the degree of certainty of what they -- they might have

opinions on. What they're doing here is showing all of the different literature supporting their findings and their views as well, and discussing these issues and complications.

Q. (By Ms. Maimbourg) Doctor, that article had to do with BMI, and it didn't even reach statistical significance, right?

A. I don't know that per se, as far as the statistical significance.

Q. And all of these statements actually had nothing to do with their -- the purpose of their study, they were just giving background right?

MS. MARIGLIANO: Object to the form.

THE WITNESS: Again, correct, they were talking about -- you said they were just regurgitating other papers, but not saying anything scientifically. I think that they're supporting -- when one writes a discussion to a paper, they're supporting either their theories or other theories with different papers in the literature.

Q. (By Ms. Maimbourg) So on the next page, when you talk about -- well, we're on 16 and 17. I didn't mean it skip too far ahead. You cite two

articles, Collinet and Lim, L-I-M, in support of your statement that a number of studies have suggested a high-risk of postoperative groin pain with the inside-out treatment.

When you use the term, postoperative groin pain here, are you referring to that six to 12-week period after implant?

A. I am here, but these particular papers also are ones that show a higher rate of long-term groin pain up to a year.

Q. So the Collinet paper only went through 12 weeks, right?

A. No, the Collinet paper is the French registry of, I think, 985 patients that reported on one-year pain rates of 3 percent. Actually, this is wrong, it's 4.7. That should be 2.7, which I think --

Q. It should be 2.7, right?

A. It's 2.7 percent, right. Yeah, and that's quoted later, so that's a typo there.

Q. And when you're saying there, what page are you referring to?

A. Page 17, about halfway down, residual rate of pain of 2.7 percent.

(Exhibit 19 was marked for identification.)

Q. (By Ms. Maimbourg) So if we look at the Collinet article, which I've placed before you as Exhibit 19, this study did not look at long-term pain, as far as I know, because if you look on page 713, they're talking about four to 12 weeks. Maybe I missed something, but this does not appear to be a long-term pain article.

A. Residual pain of 2.7 percent.

Q. It says, up above, postoperative complications occurring immediately after surgery, or by the first follow-up visit, four to 12 weeks, are shown in table 3. And table 3, residual pain, 2.7 percent. So the Collinet article is not about long-term pain.

A. Right, they quote residual pain at 12 weeks, yes.

Q. On page 18, of your report -- are you there?

A. Yes.

Q. Right about here (indicating), Ethicon should never have released an inside-out technique?

A. Okay.

Q. Do you see that? That that's your opinion, right?

A. Yes.

Q. And this is what we've been talking about here, they should never have released a -- this technique, right?

A. The inside-out technique is the TVT-O, so that's what I'm referring to.

Q. Now, you cite to Doctor -- or Professor de Leval's supposed statements on page 18. And just to be clear, you're citing an internal report, where someone is reporting what Dr. de Leval said, right?

A. Yes.

Q. Is that what it appears to be?

A. Yes.

Q. And you have this in single-spaced paragraph indented, which would imply it's a quote. Did you mean to imply it was a quote?

A. Yes.

Q. And do you practice evidence-based medicine in your job as a urogynecologist and surgeon?

A. Yes, I try to.

Q. Do you consider internal company documents

and e-mails to be a part of evidence-based machine?

A. I think that it's a part of good medicine to know all the information that you can know, so it may ultimately become part of evidence-base medicine.

Q. You've implanted devices, other than pelvic mesh?

A. Yes.

Q. Can you give me an example?

A. The InterStim device.

Q. Okay, that's a good one. Let's talk about InterStim. Either before implanting your first one, or at any time in your practice, have you ever asked the manufacturer the InterStim to give you their internal memos and e-mails regarding the development of the product?

A. No, but we expect the representatives of that company to be forthright and forthcoming with any and all information that they may have about their product, pluses or minuses, negatives or positives.

Q. When you were a consultant to AMS regarding Monarc, did you ever tell the people you were working with that they should distribute their internal company e-mails and their internal

type of different slings. So basically, my clinical background, as well as studies in the literature, as well as Ethicon's own internal documents, basically confirming that there's less risk of groin pain and issues with the sling that does not go all the way through the groin muscles.

Q. The studies in the literature, would those be studies that show what -- what particular studies in the literature? Are they all cited here in your report?

A. They should be. I mean, specifically, there's been several studies that have been comparative trials with Abbrevo versus TVT-O. And all showing various amounts of decreased risk of groin pain, both in short-term and some in the long-term. Specifically, the paper from Brown, and Shaw and Rardin showing the fact that you have 9 percent rate of groin pain with the TVT-O versus 1 percent in Abbrevo. And 25 percent of those patients that had groin pain in the TVT-O required a groin dissection. So I mean, you weigh those risk/benefits and clearly the TVT-O -- Abbrevo looks like that it's a much safer alternative.

Q. From your extensive review of the Ethicon

documents provided to you, do you know when the product went into development?

A. The product initially was basically Professor de Leval --

Q. I'm looking for a date.

A. The first time that it was brought up was 2004.

Q. When was it cleared by the FDA?

A. I believe 2009.

Q. The date I have is July 1st, 2010?

A. Okay.

Q. Would you perhaps accept my representation?

A. Sure.

Q. Do you agree that Abbrevo could not have been implanted before it was cleared by FDA?

A. I do. I believe as well, though, that it could have been developed and approved a whole lot before 2009.

Q. Do you agree that -- understanding what you're saying, you're saying that Ethicon should have put it into development sooner, but would you agree that if one of these plaintiffs in a case in which you've been identified as a general expert was

implanted before July 1 of 2010, that Abbrevo was not a safer option for her because the product was not cleared?

A. Correct.

Q. Since it's your opinion that Abbrevo is a safer option than TVT-O, I would assume that you have no criticism of its design; is that true?

A. I still am critical of passing needles through the groin. I still believe that a Mini sling that does not have to be passed -- anything passed through the groin, including needles, would be a safer alternative, as long as the clinical efficacy and the safety is there as well with that procedure. So I'm not sure if I would go as far as I don't have any criticisms of the design of the Abbrevo.

Q. Well, might you show up in a case criticizing Abbrevo, where a plaintiff is claiming injuries? I mean, would it go that far?

MS. MARIGLIANO: Object to the form. Go ahead.

THE WITNESS: At this point in time, no, I don't believe that would be the case.

Q. (By Ms. Maimbourg) Do you have any criticisms of the polypropylene mesh that is used in

the Abbrevo?

MS. MARIGLIANO: Object to the form.

THE WITNESS: I believe any criticism that I have of the mesh of TVT-O would be the same criticisms that I would have of it for the Abbrevo. I believe that since it's not as long, that there's a potential for less contraction and less kind of stretching out and curling and roping of the sling, which would be a positive for Abbrevo.

Q. (By Ms. Maimbourg) So when you were implanting the AMS devices, before they were removed from the market, they are polypropylene mesh slings, right?

A. Correct.

Q. And you didn't have any safety concerns about implanting that polypropylene mesh, did you?

A. No.

Q. Do you know anything about the difference between the polypropylene in -- in that Sparc sling and the polypropylene in any of the Ethicon products?

A. No.

Q. Now, in terms of the Abbrevo being a safer option, I know you relied on certain company

Q. Do you agree that a manufacturer does not need to tell a surgeon about the basics of sterile technique when doing surgery?

A. No, that would be inherent to their training.

Q. So we don't -- and Ethicon doesn't have to tell surgeons to wash their hands, because if they don't, it could cause a fatal infection, right?

A. Correct.

Q. And manufacturers don't have to tell surgeons that they need to consider the type of anesthesia that the patient has to have before surgery?

A. Correct.

Q. And a manufacturer doesn't have to tell a surgeon about the different risks of different surgical positions a patient could be put in?

A. No, I disagree with that one, because specifically if the position is critical for placement of that product or procedure that is going to make it safer or decrease risk of complications, then yes, they are -- they should be responsible for relaying that information to physicians.

Q. You state in your report that a physician

must be warned of a frequent -- of the frequency, severity, duration, and potential permanence of adverse events by a manufacturer. That is your opinion, correct?

A. Yes.

Q. What is the basis for your opinion that a manufacturer should warn of frequency, severity, duration, and potential permanence?

A. I think it's the surgeon's right to have that information at their hands, to be able to offer treatments and be forthcoming and forthright to their own patients, so that the patients can understand the risks and complications of any procedure they may be undergoing. So if that information is available to a manufacturer, then certainly it needs to be relayed to the physician and patients.

Q. When you were a consultant for AMS, did you advocate that position to them?

A. Yes.

Q. And did they put frequency, severity, duration, and potential permanence into their IFU?

MS. MARIGLIANO: Object to the form.

THE WITNESS: I don't know about that. I know during any type of professional education

training that I did for them, we certainly relayed all of that information to the physicians.

Q. (By Ms. Maimbourg) Right, so a manufacturer can pass on information in ways other than in the IFU, right?

A. Sure, but you weren't asking me initially whether it was just in the IFU. You said, should they give this information.

Q. Okay. My fault. So just so I'm clear you're not saying that the IFU, to be adequate, must include frequency, severity, duration, and potential permanence of adverse events?

A. I am saying, yes, it should be included in the IFU.

Q. All right. And my question to you, then, is, when you were at -- when you were assisting AMS as a consultant, are you aware of whether AMS ever included that type of this information in the IFUs for its sling products?

A. I'm not aware specifically. I don't recall the IFU details specifically.

Q. And since you've read all the literature in that big binder before you, what should those

numbers in the IFU be today for, let's say, the TVT retropubic as to the frequency of anything you want to pick right now, any adverse event?

MS. MARIGLIANO: Object to the form.

THE WITNESS: I think that it needs to be basically consistent with what's in the literature, what's in -- within the Cochrane reviews, the meta analysis, their own internal studies, their own documents. They've got internal studies that haven't been published before.

So whatever information they have, they should produce that, risk of mesh extrusion for the retropubic TVT seems to be generally in the range of 1 to 2.5 percent. That should be listed. So any of that information that's there, it should be in there.

Q. (By Ms. Maimbourg) You would agree, though, that the literature is quite varied as to how -- strike that.

You would agree with me that if you were going to go look for the frequency of a particular adverse event in the medical literature, you would find a variety of numbers?

A. Sure. So they probably should include a variety of numbers, from 1 percent to 30 percent.

Q. That's your opinion?

A. Yes.

Q. Is it your opinion that the Instructions For Use should include a statement about mesh degradation?

MS. MARIGLIANO: Object to the form.

MS. MAIMBOURG: Can you tell me how I can cure that objection?

MS. MARIGLIANO: You said how -- number one, I don't think he's offering any opinions about degradation.

MS. MAIMBOURG: Okay. If he's not, then that's swell.

Q. (By Ms. Maimbourg) Are you offering any opinions about degradation?

A. No.

Q. Are you offering any opinions about excessive and chronic foreign body reaction?

A. Where are we looking at right now, or are we?

Q. I'm just asking, in general, are you going to give expert opinions about polypropylene mesh used

in TVT-O, causing excessive and chronic foreign body reaction?

A. Only in relation to any type of chronic inflammatory effects, scarring, that occurs that would ultimately create pain from nerve or muscle damage.

Q. Are you saying that should be in the IFU?

A. I think if they have evidence of a chronic inflammatory response, and not a transitory inflammatory response, then that should be included in the IFU, yes.

Q. And based on everything you've reviewed, did Ethicon have that evidence?

A. Yes.

Q. And is what -- the evidence they had, is it included in your report at page 30?

A. Yes. Or actually, probably, I think it's on the next page as well.

Q. So you're quoting testimony from Piet Hinoul and Charlotte Owens. Is there anything else that you're relying on for your opinion?

A. I think that if you get to like tab number 20, on page 33, it gets into more of some of the different studies that were both in their internal

documents, as well as meetings with Klosterhalfen, who Professor Klosterhalfen was one of their consultants, but did a lot of publishing in the literature about chronic inflammatory reactions, mesh contraction, and subsequent issues with pain and nerve entrapment.

Q. On page 32, you talking about the 2015 Instructions For Use?

A. Yes.

Q. With respect to TVT-O, correct? And you say, all of these risks were known to Ethicon before 2015?

A. Uh-huh.

Q. Is that a yes?

A. I'm sorry, yes.

Q. Can you say that these risks were not known to doctors before 2015, can you say that?

MS. MARIGLIANO: Object to the form.

THE WITNESS: I can say that some of these risks were probably not known to some or many doctors.

Q. (By Ms. Maimbourg) Some doctors knew them all, right?

MS. MARIGLIANO: Object to the form.

THE WITNESS: Yes.

Q. (By Ms. Maimbourg) You knew them all before they were put in the IFU, right?

A. Yes.

Q. Have you done any surveys of doctors, or do you have any kind of base of knowledge to know what doctors who are implanting slings know or don't know?

A. Only based upon my experience of training and professional education of hundreds of doctors at various levels, in talking with them, and figuring out what they know and don't know, but no formal surveys, no.

Q. Is the 2015 IFU for TVT-O adequate, in your opinion?

A. I think the only thing that I would add to this would be the fact that it talks about needing multiple surgeries to remove the mesh, but it doesn't talk about the fact that it could be impossible to remove all the mesh, and that should be noted.

Q. Anything else to make it adequate?

A. I would also say the mesh is a permanent implant, significant dissection may be -- as a continuation of the -- the line that says, the mesh

is a permanent implant, and significant dissection may be required if the mesh needs to be removed. That could cause -- that this could cause, you know, permanent -- even more permanent, more pain, and more nerve damage that's permanent to the leg. In addition, saying that there's no guarantee that all the mesh can be removed, or any of the complications caused by the mesh would be reversed by some -- a major operation like that.

Q. Anything else?

A. I don't believe so.

Q. So in this section of the report, you have many things that -- and I don't have the time to actually go through every one of them, that Ethicon should have warned about. And I want to be clear, are you saying that warning should have come in the Instructions For Use?

A. Yes.

Q. And if a doctor had gone through Ethicon training, and had learned it in training, but it was not in the IFU, would you feel that Ethicon had met its duty to warn?

MS. MARIGLIANO: Object to the form.

THE WITNESS: No, because not all

CERTIFICATE

STATE OF GEORGIA:

COUNTY OF CLAYTON:

I, F. Renee Finkley, a Certified Court Reporter in and for the State of Georgia, do hereby Certify:

That prior to being examined, the witness named in the foregoing deposition was by me duly sworn to testify to the truth, the whole truth, and nothing but the truth.

That said deposition was taken before me at the time and place set forth and was taken down by me in shorthand and thereafter reduced to computerized transcription under my direction and supervision, and I hereby certify the foregoing deposition is a full, true and correct transcript of my shorthand notes so taken.

I further certify that I am not of kin or counsel to the parties in the case, and I am not in the regular employ of counsel for any of the said parties, nor am I in any way financially interested in the result of said case.

IN WITNESS WHEREOF, I have hereunto subscribed my name this 18 day of April, 2015.

F. Renee Finkley

F. Renee Finkley, RPR, RMR, CRR, CLR
Georgia CCR-B-2289